

REMARKS/ARGUMENTS

Claims 1-6 are pending in this application. Claims 7-22 have been withdrawn from consideration. Claims 1-6 have been rejected.

Claim 1 has been amended. It is respectfully submitted that the amended claim are fully supported in the specification as filed and that no new matter has been added. Support for the amendments to claim 1 is found in the specification as filed in the Examples (for use of mammalian species samples).

Information Disclosure Statement

Applicants note that the Examiner has communicated that two items, both U.S. Applications, listed on the "Submission Under MPP 609 D" page of the IDS filed March 2, 2005 have not been considered. This IDS had not earlier been considered as it was averred it does not comply with the requirements of 37 CFR 1.98(a)(iii), in that the rule requires that for each cited pending US application, the application specification including the claims, and any drawing of the application, or that portion of the application that caused it to be listed including any claims directed to that portion be provided, and that each US application listed in an IDS must be identified by the inventor, application and filing date.

Applicants have determined that that there is no copy or further record in Applicants' possession of these two patent applications, other than the mention of one of them in the 2 issued U.S. Patents in which they are referenced.

Applicants respectfully request the Examiner remove these two applications from consideration under the "Submission Under MPEP 609 D". Instead, it is requested the two U.S. Patents in which the one application (U.S. Serial No.178,202) is referenced be considered; these two patents were listed on Sheet 1 of the IDS filed March 2, 2006, under the heading "U.S. Patent Documents", and have already been considered by the Examiner on 6/9/05 as evidenced by the Examiner Initials and signature (See Exhibit A attached hereto). In addition, in US Pat. No.5,702,884, US Serial No. 178,202 was cited along with EP 0428 197 (see lines 57-60 thereof). It is to be noted that EP 0 428 197 has previously been cited in an IDS filed with the USPTO.

Claim Interpretation

The Examiner makes reference to a portion of the specification defining the term "about".

Specification

The Examiner has withdrawn his objection to the specification.

Rejection Under 35 USC §112

The Examiner has earlier withdrawn his rejection of claims 1-6 under 35 U.S.C. § 112, second paragraph.

Rejection, New Grounds

Claims 1-6 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner avers claim 1 is indefinite for reciting the phrase "contacting said precipitate with a base to raise the solution pH," (emphasis in original) because there is insufficient antecedent basis for the limitation "the solution". For the purposes of prosecution, the Examiner has construed the phrase to mean "the buffer pH".

Applicants acknowledge and agree with the construction made by the Examiner and have amended claim 1 to delete the term "solution" and replace it with the term "buffer". Antecedent basis is found for the term "buffer" in step A) of claim 1.

The Examiner further avers claim 1 is indefinite for reciting the term "polymer comprised of recurrent units", because it is unclear what unit is being recurring. Applicants have deleted the phrase "comprised of recurring units" in step A) and "comprising recurrent units" in step B), thus obviating the rejection.

The Examiner further avers claims 2-6 are indefinite by way of their dependency on claim 1. Having made the above-recited amendments to claim 1, Applicants respectfully submit that there should be no further issues and request the rejection be withdrawn as to all of claims 1-6.

The Examiner further rejected claims 1-6 under 35 USC § 112, second paragraph, because the Examiner avers the specification is not enabling for sample other than mammalian species. Applicants have amended claim 1 to recite "A method for providing a nucleic acid from a mammalian species sample not previously isolated or treated with a cell lysing reagent, comprising . . .". It is respectfully submitted that the recitation in the claim of "mammalian species" fully addresses the Examiner's rejection, and Applicants therefore respectfully submit that this rejection should be withdrawn.

Rejection Under 35 USC 102(b)

Claims 1-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by Backus et al. (U.S. Pat. No. 5,582,988, issued December 10, 1996).

The Examiner avers that Backus et al. disclose as another embodiment of their invention wherein the artisan demonstrate capture and release of nucleic acids, wherein the "sample" is calf thymus DNA solution (referencing col. 19 lines 54-67, col. 20 lines 14-15 of Backus et al.). The Examiner avers that this disclosure is clear that no previous treatment with cell lysing reagent had been performed.

Applicants have amended claim 1 to recite that the sample is one not previously isolated or treated with a cell lysing reagent. In this way it is made more clear that the "sample" that is the subject of the invention can

include those samples from mammalian species for which no extraction of nucleic acids has been made or is required prior to contact of the "sample" with the weakly basic polymer. See specification at page 9, lines 15-18. This would include the cited calf thymus DNA that by nature has already been subject to an isolation and purification procedure.

The "samples" that might be used in Applicants' invention will be typically blood or serum (specification at page 4, lines 15-18) but may include other samples not previously isolated or treated with cell lysing reagents, including other body fluids including but not limited to urine, bile, spinal fluid, bronchial lavage (BAL), colonic washes, and stool (specification at page 4 line 27 - page 5 line 3), none of which, it is plain, are isolated or treated with cell lysing reagents prior to the subject method.

Further it is recited in the specification that "Test specimens ("samples") can include body fluids or other materials containing genetic DNA or RNA.

The Examiner refers to page 13 of the Response previously filed wherein it was pointed to column 16, lines 15-65 of the Backus patent for stating that a lysis step is employed. The Examiner avers that that section of the Backus patent is drawn to preparation of copolymers and does not have any disclosure drawn toward lysis as asserted by the Applicants.

Applicants wish to correct a typographical error in the Response. The passage should have been stated as column 16, lines 59-65, not lines 15-65. The disclosure in the Backus patent at col 16 lines 59-65 indeed deal with the use of cell lysis and digestion.

In light of the foregoing amendment to claim 1 and argument distinguishing claim 1 from Backus et al., Applicants respectfully request that claims 1-6 are patentable over Backus et al. and that this rejection be withdrawn.

For the above-stated reasons and in light of Applicants' amendments made herein, it is respectfully submitted that the claims are patentable over the rejections and art cited. Applicants therefore respectfully request that the rejections be withdrawn and the claims be allowed.

The Examiner is invited to contact the Applicants' undersigned attorney to advance prosecution and discuss any issue remaining after the submission of this Amendment.

Please charge the fees due in connection with the filing of this Amendment to Deposit Account No. 10-0750/CDS0219USPCT/CKG in the name of Johnson & Johnson.

Respectfully submitted,

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